Purpose:

This document is meant to provide guidance and a template for creating study team standard operating procedures. The document should be modified for study-specific needs/requirements.

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**Study Subject Binder**

**Protocol #: \_\_\_\_\_\_\_\_\_\_\_\_\_**

**Subject ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Study Subject Binder**

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 **Study Visit Schedule from Protocol**

**Informed Consent**

* Signed, original
* All versions signed by subject
* Any modifications to informed consent document require IRB approval prior to use
* Consent Process Checklist

**Consent Process Checklist**

**Subject: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_ Time: \_\_\_\_\_\_\_\_\_**

**Who was present:**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **N/A** |
| **Discussion held in an appropriate area** |  |  |  |
| **All elements described to subject/Legally Authorized Representative (LAR)** |  |  |  |
| **Subject’s consent obtained prior to any study related procedures** |  |  |  |
| **Subject demonstrates understanding of the study (describe how this understanding was assessed):** |  |  |  |
| **Time was provided for the consenting process** |  |  |  |
| **A copy of the signed consent form was given to subject/LAR** |  |  |  |
| **Original consent form was placed with the subject’s research record** |  |  |  |
| **A copy of the consent form was placed in the subject’s medical chart**  |  |  |  |
| **When the HIPAA Research Authorization Form is separate from the consent form, a copy was given to subject/LAR**  |  |  |  |

**Comments:**

**Person who obtained consent:**

**Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Sample Questions for Assessing Understanding**

|  |
| --- |
|  |
| **Can you tell me why the research is being conducted?** |
| **Can you describe what will happen when you join the study?** |
| **Is it ok to say “no”?** |
| **Can you describe any problems or adverse events that could occur?**  |
| **Can you tell me what your choices are, other than participating in this study?** |
| **Can you describe any potential benefits from this study?** |
| **Can you describe the personal cost to you for participating in this study?** |
| **Can you describe your time commitment for this study?** |
| **Is participating in this study a reasonable decision for you right now?** |
| **What other questions do you have?** |

**Process for enrolling a non-English-speaking subject with the short form**:

1) A short form written consent document detailing the elements of informed consent is presented / translated orally to the subject or the subject’s legally authorized representative. Pre-translated short forms are available in multiple languages on the COMIRB website.

2) There must be a **witness** (independent of the study team) to the oral presentation; and

3) The COMIRB must approve a written summary (usually the full consent form) of what is presented orally to the subject or representative; and

4) The witness must sign both the short form and a copy of the summary; and

5) The person actually obtaining consent (the member of the study team) must sign a copy of the summary; and

6) The subject or representative must sign the short form consent document; and

7) The person obtaining consent should indicate on the summary the following: written summary was presented orally in subject’s native language, questions asked by subject were answered, subject agreed to participate; and

8) The signed summary and the signed short form are placed in the research record; and

9 A copy of the summary must be given to the subject or representative, in addition to a copy of the short form.

10) If HIPAA authorization is required, the following also must occur:

a. If the **combined consent/HIPAA authorization form** is used, the subject must also sign the English consent form to satisfy HIPAA authorization requirements. The HIPAA section of the consent form must have been verbally presented to the subject using a translator, and the witness must sign the form to verify that the translation is adequately reflected in the English form signed by the subject (see #4 above).

b. If a **separate HIPAA B form** is used, the subject must also sign the English HIPAA B form to satisfy HIPAA authorization requirements. The HIPAA B form must have been verbally presented to the subject using a translator, and the witness must also sign the form (next to subject's signature) to verify the translation adequately reflects the English form.

**Witnesses to Subject Consent:**

If the subject does not understand spoken English, the witness must be fluent in both English and the subject's preferred language. In this case, the witness is serving as witness to the consent process and consent documentation.

Witnesses must be impartial and independent of the study team. Such independent witnesses can include a family member of the subject, a hospital staff member who is not part of the study team, or a translator used for the consent process.

A study is permitted to utilize the short form up to three times in the same language. If a 4th subject is to be enrolled then a translation of the entire consent form should be provided to COMIRB for approval.

\*Reference COMIRB-Policy and Procedures Document 14.9 and 14.10

\*If using an IRB other than COMIRB, refer to their policies and procedures

**Supporting Documentation for**

**Case History**

(e.g., copies of clinic notes, lab reports, radiology reports, EKG)

**Eligibility Verification**

* Checklists and progress notes are examples of ways to document a subject’s eligibility to participate
* Verification should be signed and dated by PI or designee per study team Standard Operating Procedures (SOPs) or Delegation of Duties Log
* Document the reason why a subject does not meet eligibility criteria

EXAMPLE

Protocol Number: \_\_\_\_\_\_\_\_\_\_\_\_ Subject ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_

Eligibility Checklist

|  |  |  |  |
| --- | --- | --- | --- |
| **Inclusion Criteria** | Yes | No | Waived\* |
| Inclusion criterion #1 | □ | □ | □ |
| Inclusion criterion #2 | □ | □ | □ |
| **Exclusion Criteria** |
| Exclusion criterion #1 | □ | □ | □ |
| Exclusion criterion #2 | □ | □ | □ |

\*If waived, explain by whom, why and date reported to IRB: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

□ I verify that the subject meets all eligibility criteria

PI or designee\* signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\*The investigator should ensure that any individual to whom a task is delegated is qualified by education, training, and experience (and state licensure where relevant) to perform the delegated tasks.

**Adverse Event &**

**Unanticipated Problem Log**

**Adverse Event Definition:**

[**http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=312.32**](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=312.32)

**Unanticipated Problem Involving Risks to Subjects or Others Definition:**

[**http://www.hhs.gov/ohrp/policy/advevntguid.html**](http://www.hhs.gov/ohrp/policy/advevntguid.html)

**Subject ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**ADVERSE EVENTS (Anticipated and Unanticipated) &**

**UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS LOG**

*(Sample definitions to be revised as applicable)*

**Severity: Causality: Frequency: Outcome: Action taken: Category: Reported to:**

1 = mild 1 = no relation once resolved 0 = no action 1 = UAP 1 = IRB within 5 days

2 = moderate 2 = possibly related intermittent ongoing 1 = study intervention adjusted 2 = AE 2 = Sponsor

3 = severe 3 = probably related persistent resolved 2 = study intervention discontinued 3=SAE 3 = Lead site

4 = serious 4 = definitely related with sequelae 3 = concomitant medication taken 4 = FDA

deceased 5 = IRB at Cont. Review

 unknown

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **SUBJECT ID** | **EVENT DESCRIPTION** | **START DATE** | **STOP****DATE** | **UNANTICIPATED?****(Y/N)** |  **SEVERITY** | **CAUSALITY** | **FREQUENCY** | **OUTCOME** | **ACTION TAKEN** | **CATEGORY** | **REPORTED TO** | **PI INITIAL & DATE** |
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**Concomitant Medication Log**

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| **Concomitant Medication Log** |
| **IRB #:** |  |
| **Subject ID:** |  |
| **Medication Name** | **Indication** | **Dose & Units** | **Frequency** | **Start Date** | **Stop****Date** | **Ongoing at End of Trial?** |
|  |  |  |  |  |  | □Yes □No |
|  |  |  |  |  |  | □Yes □No |
|  |  |  |  |  |  | □Yes □No |
|  |  |  |  |  |  | □Yes □No |
|  |  |  |  |  |  | □Yes □No |
|  |  |  |  |  |  | □Yes □No |
|  |  |  |  |  |  | □Yes □No |
|  |  |  |  |  |  | □Yes □No |
|  |  |  |  |  |  | □Yes □No |
|  |  |  |  |  |  | □Yes □No |

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**Study Drug Accountability Log**

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| **Study Drug Accountability Log** |
| **IRB #:** |  |
| **Subject ID:** |  |
| **Drug Name:** |  |
| **Dose** | **Frequency** | **Bottle #/Box #/ Kit # (choose as appropriate)** | **Date Dispensed** | **Amount Dispensed** | **Date Returned** | **Amount Returned** | **Disposition of Returned Drug** | **Comments** |
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**Data Collection Forms**

* Signed and dated by PI or designee per study team Standard Operating Procedures (SOPs) or Delegation of Duties Log
* All sections are completed or indicated why they were left blank. Handwritten notes are acceptable.
* Include appropriate data collection tools
* Corrections made per best practice (single line through, initials and date and correct entry made)
* Document reasons for protocol deviations